

# HEALTH-RELATED QUALITY OF LIFE IN THE GERMAN EARLY BENEFIT ASSESSMENT – AN UPDATE

Kramer L<sup>1</sup>, Thaa B<sup>1</sup>, Moos M<sup>2</sup> and Esser M<sup>1</sup>

<sup>1</sup>co.value, Berlin, Germany; <sup>2</sup>Pharm-Analytics GmbH, Hamburg, Germany

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## BACKGROUND

Health-related quality of life (HRQoL) is generally defined as the personal well-being in important areas of life including physical, mental, social, family-, and work-related factors. HRQoL is measured as patient-reported outcome (PRO) via questionnaires or surveys.

The inclusion of HRQoL data is regularly requested and a deciding factor in the German early benefit assessment ("AMNOG procedure"), especially if the essential efficacy criterion of a therapy is not curation of a disease or prolongation of survival. A prolonged survival of only a few weeks or months is not considered sufficient for overall benefit if it is as the expense of HRQoL.

Both the Institute for Quality and Efficiency in Healthcare (IQWiG) and the Joint Federal Committee (G-BA) place high methodical demands on HRQoL data so that HRQoL data are only considered in a fraction of benefit assessments.

## OBJECTIVE

We analysed all benefit assessments to determine how often HRQoL data were considered in the benefit assessment (G-BA resolution) and whether consideration of HRQoL had an impact on the awarded additional benefit.

## METHODS

Using the AMNOG database from Pharm-Analytics, all terminated early benefit assessments since 01/01/2011 until 03/11/2022 were analysed. G-BA resolutions were assessed for consideration of HRQoL data. Assessments were further analysed with regard to:

- + disease area
- + extent of additional benefit

## RESULTS III

### Consideration of HRQoL data by the G-BA across disease areas

Regarding the disease areas as per definition of the G-BA, HRQoL data were considered most often in oncology in absolute numbers (n = 316), but proportionally most often in diseases of the urogenital system (63%). Of note, in the therapeutic indication psychiatric diseases no HRQoL data have been considered by the G-BA so far (Figure 3).

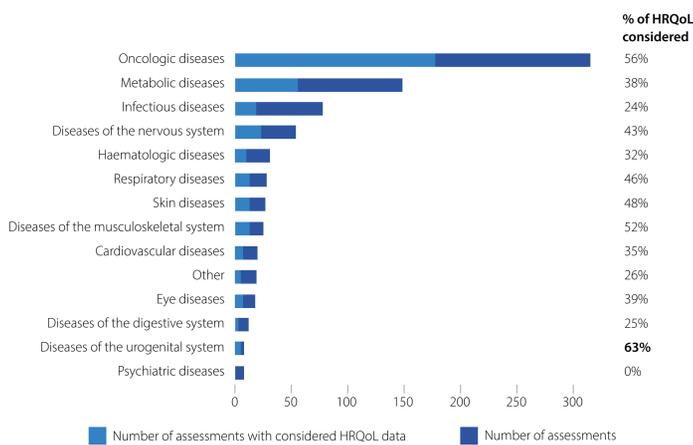


Figure 3: Number and percentage of assessments with considered health-related quality of life (HRQoL) data among number of assessments per disease area (2011–2022)

## RESULTS I

### Consideration of HRQoL data by the G-BA since the beginning of AMNOG

Since the start of the AMNOG (early benefit assessment for new drugs in Germany, since 2011) HRQoL data have been considered by the G-BA. Until 03/11/2022, a total of 793 procedures have been completed by the G-BA (all procedures with resolution by 03/11/2022). Among these, data on HRQoL were considered by the G-BA in 352 benefit assessments (44%). With the growing number of assessments, the number of procedures with considered HRQoL data grew steadily over the years. However, the percentage of assessment with considered HRQoL data among all assessments remained largely constant (Figure 1).

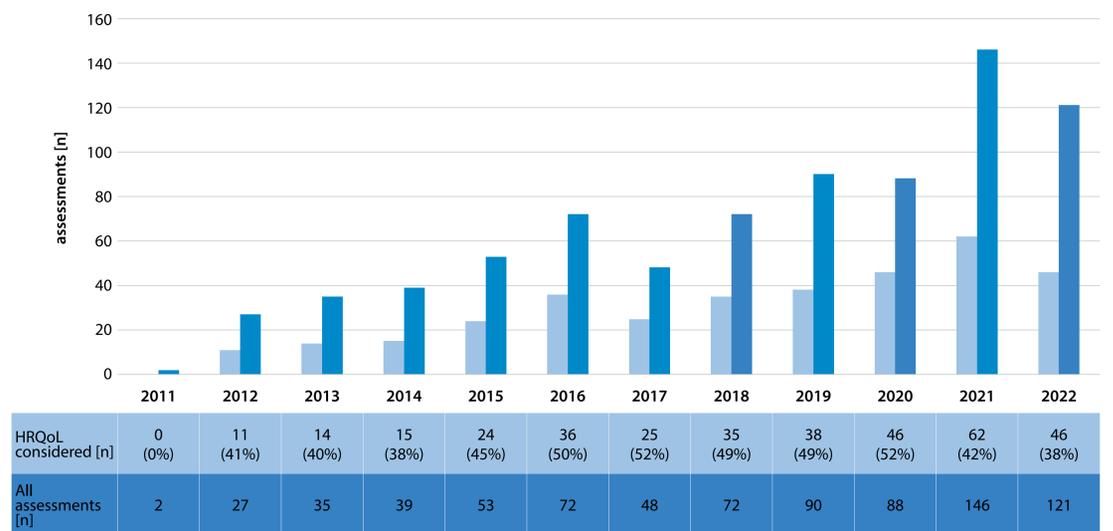


Figure 1: Proportion of benefit assessments with considered health-related quality of life (HRQoL) data among all assessments (2011–2022)

## RESULTS II

### Impact of considered HRQoL data on the extent of additional benefit

Assessments with awarded benefit in which the G-BA considered HRQoL data have more often been granted a higher additional benefit. In particular, HRQoL data were considered in 9 out of 12 assessments (75%) with the highest possible additional benefit (major additional benefit) but only in 19% of assessments (66/345) without additional benefit.

This can also be seen in the distribution of granted benefits between assessments with and without considered HRQoL data. The majority of G-BA assessments in which HRQoL data were not taken into account show no additional benefit (279/431, 65%). Conversely, assessments in which HRQoL data were considered display a nearly equal distribution among the awarded benefit categories (Figure 2).

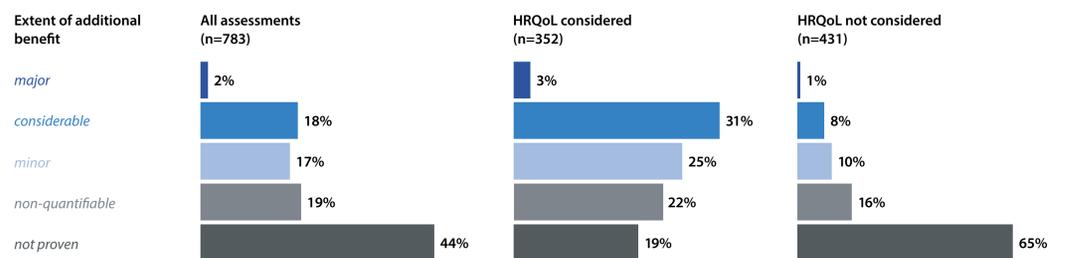


Figure 2: Distribution of awarded benefits among all assessments, assessments with considered health-related quality of life (HRQoL) and assessments without considered HRQoL 2011–2022 (percentage); benefit category "less benefit" is not shown; In case of subpopulations the highest awarded benefit is considered.

## CONCLUSIONS

- + The additional benefit tends to be higher in benefit assessments in which HRQoL data are considered. Thus, submission of HRQoL data can be beneficial in the early benefit assessment.
- + Consideration of HRQoL data by the G-BA varies between indications.
- + HRQoL data do not automatically lead to an additional benefit as the high methodical requirements posed by the G-BA need to be met.
- + In general, consideration of HRQoL data is a potential indicator of a high-quality study.